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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	4354-110	4322

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,44-49 and 52-60* is/are pending in the application.

4a) Of the above claim(s) *44-48 and 53-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 49, 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Response filed July 1, 2009 is acknowledged. Claims 50 and 51 are canceled. New claims 52-60 are presented. Accordingly, claims 1-5, 44-49 and 52-60 are now pending. However, claims 44-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. All of the claims that are presently under consideration are drawn to compositions. None of the compositions require oral administration.

The status identifier for instant claim 49 is "currently amended." No amendment to the claim is noted. Clarification is required.

In response to the provisional double patenting rejection over claims 43-45 of co-pending application S.N. 10/948,608, a Terminal Disclaimer filed July 1, 2009 is further acknowledged.

Applicants' arguments have been fully considered. Those rejections previously set forth that are not herein reiterated are withdrawn. The following objection and rejections represent the only objection and rejections presently applied to the instant claims.

Newly submitted claims 53-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Although the pharmaceutical formulation of claim 49 includes instructions for the administration of a first dosage unit and a second, subsequent, dosage unit, those instructions are distinct from those recited in the newly presented claims. Claims 53-60 require the recited compositions comprising rifalazil to have instructions wherein dosing regimens are

required for specific ranges in days of administration. Accordingly, further search and consideration are required.

Since Applicants have received an Action on the merits for the originally presented invention, i.e., compositions without "instructions," claims 1-5, and now including claim 52, and claim 49, drawn to a pharmaceutical formulation comprising rifalazil, packaged with a label or package insert providing instructions using a loading dose and a second dosage unit comprising a smaller dose of rifalazil (between 0.1 and 5 mg), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

In the last Office Action claims 1-3, 5 and 49-51 remained rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences. It was asserted Rose teaches single-dose oral administration of compositions comprising rifalazil in an amount 1 mg or 5 mg. See the Abstract and claims 1, 11 and 16 in columns 33- 34. Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher amount of active antibiotic in the first

dosage unit. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional. It has been held that Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336,70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Applicants argue Rose does not teach orally administering rifalazil on consecutive days or a tablet or capsule form of a unit dose of 1 mg. Applicants' arguments are essentially directed to intended uses of the claimed pharmaceutical compositions.

Applicants' arguments are not found persuasive. Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both

new and unobvious to one skilled in the art. *In re Hack*, 114 USPQ 161 (CCPA 1957). A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional. The oral administration of 1 mg of rifalazil in a tablet or capsule formulation is encompassed in Rose's disclosure.

Remington is properly applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflects conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

Contradistinctive to Applicants' statement on page 9 of the Response filed July 1, 2009, that new claim 52 depends from claim 4, claim 52 depends from claim 3.

The rejection of claims 1-3, 5 and 49, and presently extended to include new claim 52, under 35 U.S.C. 103, is maintained. In view of the combined teachings of Rose and Remington, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between 1-5 mg/unit. According to Remington, packaging of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

Claim4 appears to be free of the prior art.

Gidoh et al., Leprosy Review, is cited to show further the state of the art. Gidoh teaches the oral administration of rifalazil in an animal model 5 to 6 times a week and characterizes rifalazil as "extremely potent."

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 1, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614